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09/480,432	01/11/2000	RICHARD S. SURWIT	9025-7	4307

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EXAMINER
BLECK, CAROLYN M

ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 03/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/480,432	SURWIT ET AL.	
	Examiner	Art Unit	
	Carolyn M Bleck	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 7 January 2003. Claims 1-6, 8, 10-20, 22-24, 27-35, and 37-43 have been amended. Claims 7, 9, 21, 25-26, and 36 remain pending. Claims 44-73 are withdrawn from consideration.

Election/Restrictions

2. On page 15 of the response filed 7 January 2003, Applicant affirms the election of Group I (claims 1-43) for prosecution. In response, it is noted that no arguments were presents to traverse the restriction, and therefore Group II (Claims 44-73) are withdrawn from consideration in the present application.

Specification

3. The objections to the specification are hereby withdrawn due to the amendment filed 7 January 2003.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 5-7, 9-10, 14-16, 18, 29, 33-34, 36-37, 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al. (6,302,844) in view of Brown (6,161,095) and the Applicant's admission in the background of the invention of the present application (09/490432), for substantially the same reasons given in the previous Office Action (paper number 8). Further reasons appear below.

(A) Claim 1 has been amended to recite the following performed by a portable apparatus:

(a) receiving data from a patient at a portable apparatus;

(b) assessing severity of the received patient data via the portable apparatus;

(c) prompting the patient to perform a patient-administered coagulation test, via the portable apparatus, if the received patient data are assessed to be above a threshold severity level;

(d) receiving coagulation test results from the patient-administered test at the portable apparatus; and

(e) communicating the received coagulation test results of the patient administered test from the portable apparatus to a healthcare provider via a communications network (emphasis added).

It is noted the underlined portions of the claim are the newly added limitations to claim 1.

As per these limitations, Walker discloses:

(a) receiving data from a patient at a patient telemetry device, wherein an input/output circuit forms an interface between the patient telemetry device and sources of physiological data, wherein the patient data includes at least one of physiological data or parameter such as heart rate, blood pressure, temperature, perspiration level, respiratory activity, body electrical activity, and brain activity (reads on "neuropsychological data") (Fig. 1, 11-12, col. 3 lines 9-16 and 58-62, and col. 4 lines 60-67);

(b) performing an analysis by the processor of the telemetry device to determine if monitored parameters are within appropriate boundaries, wherein an alert is issued by the telemetry device in the event of a patient heart rate exceeding an upper threshold level or dropping below a threshold level, wherein multiple parameter alarms may be programmed such that particular combinations of physical parameter levels trigger specific alerts indicative of specific conditions (Fig. 1, col. 5 line 58 to col. 6 line 15, col. 8 lines 5-17, and col. 19 lines 20-31);

(c) if monitored parameters are not within appropriate boundaries, the telemetry device decides locally to dispense drugs in the case of a patient exhibiting physiological information indicative of cardiac arrest, wherein the medication reduces or mitigates any harm to the patient due to the event,

or

instructing the patient to take insulin, wherein if the blood glucose levels as measured and analyzed by the patient telemetry device, do not return to normal after a predetermined period of time, a physician or nurse is alerted (Although Walker does not

specifically recite "prompting a patient to perform a test," it is noted that the telemetry device of Walker is performing analysis locally, and is thus either dispensing a drug or instructing a patient to perform an action in response to the analysis which are both forms of "prompting" the patient. Furthermore it is well known in the art that a telemetry device such as Walker's which is monitoring blood glucose levels and is able to find that a patient requires insulin, and then "alerts a nurse or physician if the levels do not return to normal after a predetermined period of time", would also require a patient telemetry device to locally perform a second blood glucose "test" to determine that the levels have not returned to normal) (col. 6 lines 16-33, col. 8 lines 5-40, col. 19 lines 20-31, col. 20 lines 26-55);

(d) receiving data at the patient telemetry device (col. 3 lines 7-22), wherein the data includes dispensed medications (col. 6 lines 16-33); and

(e) communicating the physiological representative data including results and levels from the patient telemetry device to an expert, such as a physician or nurse, via the internet, telecommunications network, microwave link, satellite link, wireless communication medium (col. 4 lines 32-49, col. 8 lines 5-40, col. 20 lines 26-55, col. 22 lines 50-67, and col. 26 lines 55-60).

Walker fails to expressly disclose a portable apparatus (emphasis added). Brown includes a method to encourage and monitor compliance with a treatment regimen (col. 3 lines 63-67), wherein a portable device is coupled to a communication system with feedback to monitor patient compliance with and effectiveness of treatment regimens, wherein input from patients regarding treatment regimens can be recorded,

reviewed, and analyzed, wherein treatment regimens in response to feedback from patient can be altered, wherein the medication regimen includes obtaining medicine, taking medicine, taking medicine with another substance such as food or water, not taking medicine with another substance such as alcohol or incompatible medications, or obtaining a prescription refill, a physical therapy regimen including exercising, stretching, changing position, or changing work routine, and a psychological regimen including repeating an affirmation, meditation, self-hypnosis or other mental activity, or a self-help regimen such as weight loss including drinking water or eating a snack (Fig. 1-2, col. 1 line 57 to col. 2 line 67, col. 3 lines 1-17, col. 5 lines 3-23, and col. 6 line 55 to col. 8 line 31).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include the aforementioned components, specifically the portability of the patient apparatus, of Brown within the method of Walker with the motivation of ensuring patients are restricted as little as possible regarding their activities and movements (Brown; col. 1 lines 57-60), encouraging and assuring patients comply with the requirements of a treatment regimen (Brown; col. 1 lines 24-60) thus improving the health care provided to patients and allowing patients to be remotely monitored in such a way as to make a preliminary decision about whether a physician should be contacted (Walker; col. 1 lines 51-63) thus reducing the cost of providing health care services (Brown; col. 2 lines 22-26).

Although Walker includes instructing a patient to perform an action as discussed above, Walker fails to expressly disclose monitoring anticoagulation therapy using a

specific medication regimen and coagulation test. In the background of the invention of the present application, it is disclosed that anticoagulation therapies include warfarin and other vitamin K antagonists, heparin and similar glucosaminoglycans, and direct thrombin inhibitors (e.g., hirutin, melagatgran) and the tests include prothrombin (PT), partial thromboplastin time (PTT), activated clotting time (ACT), specific heparin or low molecular weight heparin assays, ecarin clotting time (ECT), thrombin clotting time, and PT or PTT (pg. 6). Further, Applicant discloses in the background of the invention that home monitoring devices have been developed and marketed to collect physiologic data and report the data to a physician, wherein the devices include home coagulation time monitors for patients undergoing anticoagulation therapy (pg. 4). At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include monitoring the aforementioned therapies and tests disclosed in the background of the invention within the method taught by Walker with the motivation of increasing patient compliance with complex treatment regimens and reducing the number of potential side effects by allowing for remote monitoring of treatment regimens (Walker; col. 1 lines 10-64, col. 2 lines 8-27, and col. 3 lines 9-26).

In addition, insofar as Applicant recites "selected from the group consisting of..." and "at least one of...", it is irrelevant whether or not Walker or Brown disclose every single statement recited in the claim.

(B) As per claim 5, Brown discloses receiving from the patient device, information about patient compliance with the treatment regimen including medication taken by the

patient, physical therapy regimen, psychological therapy, self-help regimen, and tests during a time interval dictated by the treatment regimen (col. 2 lines 1-13, col. 5 lines 8-23, col. 5 line 48 to col. 6 line 14, and col. 7 line 37 to col. 8 line 31). The remainder of claim 5 repeats the same limitations of claim 1, and is therefore rejected for the same reasons given above for claim 1, and incorporated herein. The motivation for combining Brown with Walker is given above in claim 1, and incorporated herein.

(C) As per claim 6, Walker discloses receiving data from a patient telemetry device at a central server (col. 8 lines 5-40 and col. 20 lines 26-55) and then transmitting a copy of at least a portion of the patient's medical history and a description of the current pattern or data aberration to the medical expert via a network if at least one physiological data or parameter is not within appropriate or "normal" parameter boundaries (Fig. 11-12, col. 1 line 65 to col. 2 line 67, col. 3 line 55 to col. 4 line 48, col. 5 line 57 to col. 6 line 15, col. 7 lines 12-63). The remainder of claim 6 repeats the same limitations of claim 1, and is therefore rejected for the same reasons given above for claim 1, and incorporated herein.

(D) Claims 7 and 9 have not been amended and are rejected for the same reasons given in the previous Office Action (paper number 8; pages 10-11).

(E) The amendments to claims 10, 14-16, and 18 reflect the same changes made to claims 1, 5-7, and 9, discussed above, and are therefore rejected for the same reasons

given above for claims 1, 5-7, and 9 in addition to the rejections made for claims 1, 5-7, 9-10, 14-16, and 18 in the prior Office Action (paper number 8; section 9; pages 4-12).

(F) The amendments to claims 29, 33-34, 37, and 41-42 reflect the same changes made to claims 1, 5-7, 9-10, 14-16, and 18, discussed above, and are therefore rejected for the same reasons given above for claims 1, 5-7, 9-10, 14-16, and 18 in addition to the rejections made for claims 29, 33-34, 37, and 41-42 in the prior Office Action (paper number 8; section number 11; pages 21-28).

(G) Claim 36 is rejected for the same reasons given for claim 9 in the previous Office Action (paper number 8; pages 10-11).

6. Claims 2-4, 8, 11-13, 17, 30-32, 35, 38-40, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al. (6,302,844), Brown (6,161,095), and the Applicant's admission in the background of the invention of the present application (09/490432) as applied to claims 1, 10, 29, and 37 for substantially the same reasons given in the previous Office Action (paper number 8), and further in view of Worthington et al. (6,379,301). Further reasons appear below.

(A) As per claim 2, the relevant teachings of Walker, Brown, and the Applicant's background of the invention, and the motivation for their combination is as discussed in the rejections above, and incorporated herein.

Claim 2 has been amended to recite the following:

assessing severity of the received coagulation test results from the patient-administered coagulation test via the portable apparatus;

modifying the patient-administered medication regimen via the portable apparatus if the received coagulation test results from the patient administered coagulation test are assessed to be above a threshold severity level; and

communicating the modified patient-administered medication regimen to the patient.

Brown discloses modifying the treatment regimen used by a patient and sends the treatment regiment to the patient device using a communication network (col. 7 lines 49-62). However, Walker, Brown, and the Applicant's background of the invention fail to expressly disclose the steps of assessing severity of the received coagulation test results from the patient-administered coagulation test via the portable apparatus, and modifying the patient-administered medication regimen via the portable apparatus if the received coagulation test results from the patient administered coagulation test are assessed to be above a threshold severity level.

Worthington includes a patient-operated apparatus for measuring a blood sample of the patient, and for producing from a measurement of the blood a value, wherein a target range is determined, and wherein if the blood value falls outside of the range when performing the test, corrective action is determined by the processor of the apparatus, and the corrective action is recommended to the patient via the apparatus (col. 4 lines 1-60).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the aforementioned components of Worthington within the method taught collectively by Walker, Brown, and the Applicant's background of the invention with the motivation of allowing a patient to make a timely correction when blood tests lie outside of a range (Worthington; col. 3 lines 54-64).

(B) As per claims 3-4, Worthington discloses a healthcare provider computer in communication with the apparatus for receiving from the apparatus values and corrective actions (col. 4 lines 48-60). The remainder of claims 3-4 repeats the same limitations of claim 1-2, and is therefore rejected for the same reasons given above for claim 1-2, and incorporated herein. The motivation for combining Worthington within Walker, Brown, and the Applicant's background of the invention is given above in claims 1 and 2, and incorporated herein.

(D) As per claim 8, Brown discloses sending information including the supply and use of pharmaceuticals and medication dosage to the patient device in response to reviewing and evaluating that the patient did not comply with the treatment regimen in the time interval dictated by the treatment regimen (col. 5 lines 8-23, col. 5 line 48 to col. 6 line 14, and col. 7 line 49 to col. 8 line 31). The remainder of claim 8 repeats the same limitations of claim 1, and is therefore rejected for the same reasons given above for claim 1, and incorporated herein.

(E) The amendments to claims 11-13 and 17 reflect the same changes made to claims 2-4 and 8, discussed above, and are therefore rejected for the same reasons given above for claims 2-4 and 8 in addition to the rejections made for claims 11-13 and 17 in the prior Office Action (paper number 8; section 9; page 12).

(F) The amendments to claims 30-32, 35, 38-40, and 43 reflect the same changes made to claims 2-4, 8, 11-13, and 17, discussed above, and are therefore rejected for the same reasons given above for claims 2-4, 8, 11-13, and 17 in addition to the rejections made for claims 30-32, 35, 38-40, and 43 in the prior Office Action (paper number 8; section number 11; pages 21-28).

7. Claims 19-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al. (6,302,844) in view of Brown (6,161,095), the Applicant's admission in the background of the invention of the present application (09/490432), and Surwit et al. (6,024,699), for substantially the same reasons given in the previous Office Action (paper number 8). Further reasons appear below.

(A) Claims 19-28 have been amended to recite a portable patient apparatus. As per this limitation, Brown discloses a method to encourage and monitor compliance with a treatment regimen (col. 3 lines 63-67), wherein a **portable device** is coupled to a communication system with feedback to monitor patient compliance with and effectiveness of treatment regiments, wherein input from patients regarding treatment

regimens can be recorded, reviewed, and analyzed, wherein treatment regimens in response to feedback from patient can be altered, wherein the medication regimen includes obtaining medicine, taking medicine, taking medicine with another substance such as food or water, not taking medicine with another substance such as alcohol or incompatible medications, or obtaining a prescription refill, a physical therapy regimen including exercising, stretching, changing position, or changing work routine, and a psychological regimen including repeating an affirmation, meditation, self-hypnosis or other mental activity, or a self-help regimen such as weight loss including drinking water or eating a snack (Fig. 1-2, col. 1 line 57 to col. 2 line 67, col. 3 lines 1-17, col. 5 lines 3-23, and col. 6 line 55 to col. 8 line 31).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include the aforementioned components, specifically the portability of the patient apparatus, of Brown within the method of Walker with the motivation of ensuring patients are restricted as little as possible regarding their activities and movements (Brown; col. 1 lines 57-60), encouraging and assuring patients comply with the requirements of a treatment regimen (Brown; col. 1 lines 24-60) thus improving the health care provided to patients and allowing patients to be remotely monitored in such a way as to make a preliminary decision about whether a physician should be contacted (Walker; col. 1 lines 51-63) thus reducing the cost of providing health care services (Brown; col. 2 lines 22-26).

The remaining features of claims 19-28 are rejected for the reasons set forth in the previous Office Action, and incorporated herein (paper number 8; section 10; pages 13-21).

Response to Arguments

8. Applicant's arguments with respect to claims 1-43 have been considered but are moot in view of the new ground(s) of rejection.

9. Applicant's arguments filed 7 January 2003 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 7 January 2003.

(A) At pages 15-16 of the 7 January 2003 response, Applicant argues that in order to establish a prima facie case of obviousness, the prior art reference, or references when combined, must teach or suggest all the recitations of the claims, and there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Further Applicant argues that as recently emphasized by the Court of Appeals for the Federal Circuit, to support combining references, evidence of suggestion, teaching, or motivation to combine must be ***clear and particular.***

In response, the Examiner respectfully submits that obviousness is determined on the basis of the evidence as a whole and the relative persuasiveness of the

arguments. See *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); *In re Hedges*, 783 F.2d 1038, 1039, 228 USPQ 685,686 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785,788 (Fed. Cir. 1984); and *In re Rinehart*, 531 F.2d 1048, 1052, 189 USPQ 143,147 (CCPA 1976). Using this standard, the Examiner respectfully submits that he has at least satisfied the burden of presenting a *prima facie* case of obviousness, since she has presented evidence of corresponding claim elements in the prior art and has expressly articulated the combinations and the motivations for combinations that fairly suggest Applicant's claimed invention (see paper number 8 and 10). Note, for example, the motivation explicitly stated at the last full paragraph of page 5 of the present Office Action (i.e., "...ensuring patients are restricted as little as possible regarding their activities and movements (Brown; col. 1 lines 57-60), encouraging and assuring patients comply with the requirements of a treatment regimen (Brown; col. 1 lines 24-60) thus improving the health care provided to patients and allowing patients to be remotely monitored in such a way as to make a preliminary decision about whether a physician should be contacted (Walker; col. 1 lines 51-63) thus reducing the cost of providing health care services (Brown; col. 2 lines 22-26). ...") which is based on the teachings of the applied prior art.

(B) At pages 16-18 of the 7 January 2003 response, Applicant summarizes the teachings of the applied references individually. In addition, Applicant argues features that have been recently added to the claims in the amendment filed 7 January 2003 are

missing from the teachings of Walker and Brown. Further, Applicant argues that the applied references fail to teach or suggest certain features.

In response, the Examiner respectfully submits that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In particular, the teachings that Applicant argues are missing from the Walker reference are clearly disclosed in the respective teachings of Brown, the Background of the Applicant's Invention, and/or Worthington and Surwit, when considered collectively with that of Walker, as discussed in detail within a prior Office Action (paper number 8) and in the preceding rejections, and incorporated herein.

Further, the features newly added and entered in the amendment filed 7 January 2003, they have been shown to be fully disclosed by or obvious in view of the collective teachings of Walker, Brown, the Background of the Applicant's Invention, and/or Worthington and Surwit, as discussed above in detail within the preceding sections of the present Office Action. In particular, the features of ***a portable apparatus that assesses severity of data received from a patient*** and ***a portable apparatus receiving coagulation test results from the patient-administered test*** as discussed on page 19 of the response filed 7 January 2003 have been discussed above at pages 1-7, section 5(A) of the present Office Action.

In addition, it is respectfully submitted that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of

the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

In addition, the Examiner respectfully submits that the issue at hand is not whether the applied prior art specifically teaches a method of monitoring anticoagulation therapy of a patient performed by a portable apparatus, *per se,* but rather, whether or not the prior art, when taken in combination with the knowledge of average skill in the art, would put the artisan in possession of this feature. Regarding this issue, it is well established that references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures *In re Bozek*, 163 USPQ 545 (CCPA 1969). The issue of obviousness is not determined by what the references expressly state but by what they would reasonably suggest to one of ordinary skill in the art, as supported by decisions in *In re DeLisle* 406 Fed 1326, 160 USPQ 806; *In re Kell, Terry and Davies* 208 USPQ 871; and *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ 2d 1596, 1598 (Fed. Cir. 1988) (citing *In re Lalu*, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1988)). Further, it was determined in *In re Lamberti et al*, 192 USPQ 278 (CCPA) that:

(i) obviousness does not require absolute predictability;

(ii) non-preferred embodiments of prior art must also be considered; and

(iii) the question is not express teaching of references, but what they would suggest.

According to *In re Jacoby*, 135 USPQ 317 (CCPA 1962), the skilled artisan is presumed to know something more about the art than only what is disclosed in the applied references. In *In re Bode*, 193 USPQ 12 (CCPA 1977), every reference relies to some extent on knowledge of persons skilled in the art to complement that which is disclosed therein.

According to *Ex parte Berins*, 168 USPQ 374 (Bd. Appeals), there is no statutory limitation as to the number of references that may be used to demonstrate obviousness...not what references expressly state but what they would reasonably suggest to one of ordinary skill in the art. In *In re Conrad*, 169 USPQ 170 (CCPA), obviousness is not based on express suggestion, but what references taken collectively would suggest.

In this case, Walker discloses a patient telemetry device for receiving data from a patient, performing an analysis by the processor of the telemetry device to determine if monitored parameters are within appropriate boundaries, if monitored parameters are not within appropriate boundaries, the telemetry device decides locally to dispense drugs in the case of a patient exhibiting physiological information indicative of cardiac arrest, or instructs the patient to take insulin, wherein if the blood glucose levels as measured and analyzed by the patient telemetry device, do not return to normal after a predetermined period of time, a physician or nurse is alerted, receiving data at the patient telemetry device, and communicating the physiological representative data including results and levels from the patient telemetry device and Brown discloses a portable device coupled to a communication system with feedback to monitor patient

compliance with and effectiveness of treatment regimens. It is the position of the Examiner that the skilled artisan would be in possession of a portable patient apparatus, such as that claimed in the amendment filed 7 January 2003, when considering the teachings of Walker and Brown, collectively, in combination with the knowledge of average skill in the art, for at least the reason that the skilled artisan would readily recognize that a portable apparatus would ensure that patients are restricted as little as possible regarding their activities and movements.

As such, it is respectfully submitted that Applicant appears to view each of the applied references separately, in a vacuum, without considering the knowledge of average skill in the art, and that such piecemeal analysis is improper.

With respect to the limitations recently added to the claims in amendment filed 7 January 2003, the Examiner respectfully submits that all features presently claimed in claims 1-6, 8, 10-20, 22-24, 27-35, and 37-43 are disclosed by the collective teachings of Walker, Brown, the Applicant's background of the invention, Surwit, and/or Worthington references as discussed in detail in sections 4-7 above in addition to the reasons set forth in the prior Office Action (paper number 8; sections 8-11 pages 4-28), and incorporated herein.

In response to the Applicant's argument that the applied references are silent with respect to the element of "prompting the patient to perform a patient-administered coagulation test if the received patient data are assessed to be above a threshold severity level, the Examiner respectfully notes that the cited reference was never applied as a reference under 35 U.S.C. 102 against the pending claims. As such, the

Examiner respectfully submits that the issue at hand is not whether the applied prior art specifically teaches the claimed features, *per se*, but rather, whether or not the prior art, when taken in combination with the knowledge of average skill in the art, would put the artisan in possession of these features. In reference to Applicant's specific arguments with respect to the Walker reference, the Examiner respectfully submits that Applicant's statements appear to be misdescriptive of the full teachings of Walker in combination with Brown and the Background of the Applicant's Invention. Moreover, the Examiner respectfully submits that obviousness is determined on the basis of the evidence as a whole and the relative persuasiveness of the arguments. See *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2D 1443, 1444 (Fed. Cir. 1992); *In re Hedges*, 783 F.2d 1038, 1039, 228 USPQ 685, 686 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984); and *In re Rinehart*, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976).

In particular, Walker includes if monitored parameters are not within appropriate boundaries, the telemetry device decides locally to dispense drugs in the case of a patient exhibiting physiological information indicative of cardiac arrest, wherein the medication reduces or mitigates any harm to the patient due to the event, or instructing the patient to take insulin, wherein if the blood glucose levels as measured and analyzed by the patient telemetry device, do not return to normal after a predetermined period of time, a physician or nurse is alerted (col. 6 lines 16-33, col. 8 lines 5-40, col. 19 lines 20-31, col. 20 lines 26-55). Although Walker does not specifically recite "prompting a patient to perform a test," it is noted that the telemetry device of Walker is

performing analysis locally, and is thus either dispensing a drug or instructing a patient to perform an action in response to the analysis which are both forms of "prompting" the patient. Furthermore, a telemetry device such as Walker's which is monitoring blood glucose levels and is able to find that a patient requires insulin, and then "alerts a nurse or physician if the levels do not return to normal after a predetermined period of time", suggests that the telemetry device performs a first blood glucose test to determine whether or not a patient requires insulin and then would also require the device to locally perform a second blood glucose "test" to determine that the levels have not returned to normal in order to alert a physician or nurse. In addition, the Applicant's Background of the Invention was relied upon for disclosing an anticoagulation test. Thus the proper combination of the applied references would be the incorporation of the Applicant's Background of the invention anticoagulation test within the telemetry device of Walker.

In light of the above, the Examiner respectfully submits that it is sufficient to demonstrate that the prior art meets the limitations as claimed, whether by a single instance or scenario, or in every possible preferred embodiment, since it was determined in *In re Lamberti et al*, 192 USPQ 278 (CCPA) that:

(i) obviousness does not require absolute predictability;

(ii) non-preferred embodiments of prior art must also be considered; and

(iii) the question is not express teaching of references, but what they would suggest.

Thus, the fact situations provided by the Examiner, no matter how infrequent or occasional they may be, are indeed embodiments that Applicant is expected to have considered. As such, since Applicant fails to expressly recite limitations that provide a patentable distinction over such fact situations, it is respectfully submitted that prior art either reads on or makes obvious Applicant's claimed limitations.

(C) Applicant's remaining arguments given at pages 19-20 of the response filed 7 January 2003 rely upon or rehash the issues addressed above, and are therefore moot in view of the responses given in sections 9(A) – 9(B) above, and incorporated herein.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to the Applicant's disclosure. The cited but not applied prior art teaches a patient compliance monitor (6,514,200), an apparatus for non-intrusively measuring health parameters of a subject (6,524,239), and an in-home health care system (6,525,670).

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Bleck whose telephone number is (703) 305-3981. The Examiner can normally be reached on Monday-Thursday, 8:00am – 5:30pm, and from 8:30am – 5:00pm on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached at (703) 305-9588.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist whose telephone number is (703) 306-1113.

13. **Any response to this action should be mailed to:**

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Or faxed to:

(703) 305-7687	[Official communications; including After Final communications labeled "Box AF"]
(703) 746-8374	[Informal/ Draft communications, labeled "PROPOSED" or "DRAFT"]

Hand-delivered responses should be brought to Crystal Park 5, 2451 Crystal Drive, Arlington, VA, 7th Floor (Receptionist).

CB
CB
March 4, 2003

DINH X. NGUYEN
PRIMARY EXAMINER